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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/20/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/463,474

Applicant(s)

SINN ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,13,15,16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) 4,7,9 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 13 is/are rejected.
- 7) ☐ Claim(s) 5,6,8,10,15 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Pursuant to the directives of paper No. 22 (filed 3/6/03), claims 1, 2, 4, 8-10 have been amended. Claims 1, 2, 4-10, 13, 15, 16, 18 remain pending. Claims 4, 7, 9, 18 are withdrawn from consideration, since these claims do not encompass the elected specie. Claims 1, 2, 5-6, 8, 10, 13, 15, 16 are examined in this Office action. Applicants' arguments filed 3/6/03 have been considered and found persuasive. The previously imposed rejections are withdrawn.

Claims 5, 6, 8, 10, 15, 16 are objected to because of their dependence on rejected claims.

✱

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 13 are rejected under 35 U.S.C. §102(b) as being anticipated by Carlsson (USP 4,231,999).

Carlsson discloses (col 15, line 46 to col 16, line 15) a method for preparing a conjugate of albumin in which fluorescein is bonded via a linker to albumin. The conjugate can be represented as follows:

Fluor-GSH-L-albumin

wherein "Fluor" represents fluorescein, "GSH" represents glutathione, and "L" represents the following linking moiety: $-S-CH_2-CH_2-CO-$. The moiety "Fluor-GSH-L-" is bonded to albumin via an amide linkage.

The instant claims require that a "fluorescent moiety" be bonded to the carrier via an amide bond; the rejected claims, however, do not impose any limitations on the structure of the "fluorescent moiety". The claims are anticipated because the "fluorescent moiety" can be "Fluor-GSH-L-". Carlsson does not disclose that the albumin / fluorescein conjugate can be used for "distinguishing cancerous or inflamed tissue from healthy tissue", but this is only an intended use limitation, and moreover, the recited property is inherent in the disclosed conjugate.

Thus, the claims are anticipated.

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The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned

at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Tryggvason (USP 4,677,058).

Tryggvason discloses (col 4, lines 13-24) that fluorescein-conjugated anti-rabbit IgG could be used to detect the presence of malignant tumor cells. The fluorescein conjugate was prepared by reacting the isothiocyanate of fluorescein (FITC) with immunoglobulin G. The reference does not disclose that the fluorescent moiety was bonded to the IgG by an amide linkage.

Since the disclosed conjugate can be used to detect the presence of malignant tumor cells, the disclosed conjugate meets the requirement of claim 1 for a conjugate which can "distinguish ^{cancerous} ~~cancerous~~ ... tissue from healthy tissue". With respect to another limitation, claim 1 requires that the fluorescent moiety is bonded to the carrier protein by an amide linkage. Reaction of an aryl isothiocyanate (such as FITC) with a protein that contains lysine groups results in a thiourea bond, not an amide bond. However, the lysine which bears the fluorescein moiety is itself bonded, via amide linkage, to the remainder of the protein. Claim 1 does not impose any limitations on the structure of the "fluorescent moiety". The "fluorescent moiety", therefor, could be a fluorescein conjugated to a single lysine. Thus, it would have been obvious to one of ordinary skill that when the

"fluorescent moiety" is fluorescein conjugated to a single lysine, the fluorescent moiety is bonded via amide linkage to a carrier protein.



No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

D. Lukton 5/14/03

Christopher S. F. Low
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